UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,434	01/13/2006	Cinderella Christina Gerhardt	f7683 (V)	6803

201 7590 03/13/2009

UNILEVER PATENT GROUP
800 SYLVAN AVENUE
AG West S. Wing
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
03/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,434	GERHARDT ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12,13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12,13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 14, 2009 has been entered. Claims 1, 3-10, 12-13 and 15-17 are pending in this application and examined on the merits in this office action.

Maintained Rejection

35 U.S.C. 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3-10, 12-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reimer et al (WO 01/37850) in view of O'Callaghan et al (WO 93/04593).

6. Reimer et al teach a method of treatment of diabetes comprising administering an effective amount of a composition comprising sweet or acid whey proteins or hydrolysates (page 1, lines 11-14). The sweet or acid whey taught by Reimer et al comprises whey protein hydrolysates and minor proteins that remain intact (page 8, lines 4-8) and is capable of stimulating the release of active GLP-1 in the NCI-H716 intestinal cell line (page 15, lin3s 11-23). The composition taught by Reimer et al may be in the form of fermented milk, yogurt, cheese, confectionary bar, breakfast cereal flakes or bars, drinks, milk powders, soy-based products or nutritional supplements for clinical nutritional supplements (page 10, lines 29-33). Reimer et al do not teach that the average molecular weight of the whey protein hydrolysates is in the range of 1000-12000 Daltons, that the whey protein hydrolysates comprises hydrolysates of β-

lactoglobulins, α-lactalbumin or a mixture thereof, or that the degree of hydrolysis is in the range of 0.1% to 80% by weight.

7. O'Callaghan et al teach hypoallergenic whey protein hydrolysates for use in infant formula (page 6, line 28) prepared by proteolytic treatment (page 6, line 33). The whey protein hydrolysate has an average molecular weight of 1854.7 Daltons (the weighted average molecular weight based on the molecular weight distribution reported in Table 4). The whey protein hydrolysates taught by O'Callaghan et al comprises lactalbumin hydrolysates (Table 4). Assuming a molecular weight of 16000 Daltons for α-lactalbumin, the degree of hydrolysis of the whey protein in this composition is 11% (Table 4).

8. It would have been obvious to use the hypoallergenic whey protein hydrolysates taught by O'Callaghan et al in place of the sweet or acid whey protein in the method of treating diabetes as taught by Reimer et al. In particular, it would have been obvious to orally administer this composition to subjects suffering from Type 2 diabetes or glucose intolerance and in doing so, improve or prevent a decline in mental performance, provide a sustained feeling of energy and maintain or provide a feeling of well-being during the post-prandial period in the same subjects. The skilled artisan would have been motivated to substitute the hypoallergenic whey protein hydrolysates taught by O'Callaghan et al for the sweet or acid whey protein in the method of treating diabetes taught by Reimer et al based on the teaching of Reimer et al that the sweet or acid whey can be further hydrolyzed, for example to prepare a hypoallergenic whey protein hydrolysate (page 8, lines 16-18). The skilled artisan would have been motivated to

target Type 2 diabetic patients with impaired glucose tolerance (diabetics) based on the teachings of Reimer et al. Specifically, Reimer et al discuss that Type 2 diabetic suffer from insulin resistance and that diabetics in general are aided by receiving controlled amounts of insulin (page 1, lines 31-36). Reimer et al then comment that insulin injection is not safe, convenient or acceptable to the patient as oral administration (page 2, lines 1-6). Reimer et al go on to say that compositions that induce the release of GLP-1, a potent insulin secretagogue (page 2, line 10), can be used to improve glucose homeostasis in vivo. Finally, Reimer et al teach that sweet or acid whey, which can be administered orally, is capable of stimulating the release of active GLP-1 in the NCI-H716 intestinal cell line (page 15, lines 11-23). There would have been a reasonable expectation that the substitution of the whey protein hydrolysates taught by O'Callaghan et al for that of Reimer et al would be successful given that the whey protein hydrolysates taught by O'Callaghan et al is also designed for oral administration to humans.

9. The combination of the Reimer et al and O'Callaghan et al references satisfy all of the limitations of claim 1: an edible composition comprising whey protein hydrolysates with an average molecular weight between 1000-12000 Daltons is orally administered to subject (any subject). Because the composition and patient population (anybody, including subjects suffering from Type 2 diabetes and infants) are same as to the claimed invention, the effects of improving or preventing a decline in mental performance, providing a sustained feeling of energy and maintaining or providing a feeling of well-being during the post-prandial period will result. In other words, any

person administered the composition comprising the whey protein hydrolysates would benefit from improvement in mental performance, including infants. With respect to claim 8, the whey protein hydrolysate comprises α-lactalbumin. With respect to claim 3, the whey protein hydrolysate has a degree of hydrolysis in the range of 1% to 20%. With respect to claims 5-9, 12 and 13, the compositions may be in the form of a powder, liquid concentrate or ready-to-drink beverage, fermented milk, yogurt, cheese, confectionary bar, breakfast cereal flakes or bars, drinks, milk powders, soy-based products or nutritional supplements for clinical nutritional supplements and are therefore designed a meal replacement products to be used as part of a diet plan to maintain glucose homeostasis (Reimer et al, page 3, line 4). Regarding claims 4 and 15, Reimer et al teach that compositions comprise at least 0.01% sweet or acid whey by weight which differs from the claimed range of 0.1% to 80%, preferably 1% to 30%. It would have been obvious to the skilled artisan to optimize the concentration of whey protein hydrolysates in the composition in order to effectively induce GLP-1 secretion and control glucose homeostasis in the subject. With respect to claims 16 and 17, O'Callaghan et al teach compositions comprise a pH of 6.42% (Table 3) and maintaining pH at 8.0 (page 15, lines 30-32) and the degree of hydrolysis of the whey protein in this composition is 11% (Table 4). It would have been obvious to the skilled artisan to optimize the concentration of whey protein hydrolysates in the composition in order to effectively induce GLP-1 secretion and control glucose homeostasis in the subject. Section 2144.05 of the MPEP states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the

prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

10. Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Applicant's Arguments

11. Applicant argues that "The molecular weight distributions of the hypoallergenic whey protein hydrolysates are depicted in the Tables 2, 4, 6, 8 and 10, and O'Callaghan et al teach it is desirable to have a certain proportion (approximately 8-15%) of the total polypeptide mixture in the region of 50,000 – 5,000 Daltons to provide emulsion stability in the final infant formula." Applicant argues that "The table clearly shows the difference between O'Callaghan's table and present claim 1 at >10,000 Daltons and < 2,0000 Daltons." Applicant argues that "substitution of the whey protein hydrolysates taught by O'Callaghan et al for that of Reimer et al would result in the use of a whey protein hydrolysate that does not exhibit the MW distribution profile that is recited by the present claims." Applicant argues that "the Office points to no teaching by Reimer et al that GLP-1 secretion can be optimized by varying the MW-distribution of the hydrolysates. Consequently, it would appear that the recited argumentation that it would have been obvious to maximize GLP-1 secretion by optimizing the concentrations of the whey protein MW-profile, enjoys the benefit of proscribed hindsight."

12. Applicant's arguments have been fully considered but have not been found persuasive because the prior arts combined teaches the present invention. Reimer et al teach that milk protein hydrolysate can induce the release of GLP-1 and it can be used to improve glucose homeostasis *in vivo* (page 3, lines 1-2). Furthermore, Reimer et al teach that the term "milk protein hydrolysates" is taken to mean milk proteins that have been subjected to any sort of hydrolysis (page 6, lines 18-19), and "sweet whey" and "acid whey" are also considered to be possible milk protein hydrolysates, because they are the product of enzymatic or acid hydrolysis of milk proteins (page 6, lines 24-26). Reimer also indicates that sweet and acid whey stimulate the release of active GLP-1 in the NCI-H716 intestinal cell line (See results section). Thus, this implies that any sweet and acid whey stimulates the release of active GLP-1. Furthermore, Reimer et al teach that "it is also clear to the skilled person, that protein hydrolysate present in sweet or acid whey can be further hydrolyzed, for example to prepare a hypoallergenic whey protein hydrolysate...such a hydrolysate may then be used as a liquid or it may be dried and incorporated in numerous food products" (page 8, lines 16-22). Additionally, the reference teaches an edible composition comprising whey protein hydrolysate. This would necessarily have the capability of inducing the cellular release of glucagon-like-peptides and cholecystokinins.

Furthermore, O'Callaghan et al teach that modification of food proteins by enzymatic hydrolysis is well documented and can be used to reduce the allergenicity of bovine milk proteins for inclusion in hypoallergenic baby formulae and special dietetic foods (page 2, lines 30-33). The instant claims do not recite the patient population,

therefore, anyone orally administered the composition comprising whey protein hydrolysates would necessarily have improvement in mental performance, including infants. An infant would benefit from the administration of the edible composition, since it would necessarily improve mental performance. Furthermore, O'Callaghan et al teach that Asselin et al (1989) demonstrated that hydrolysis of whey proteins with pepsin followed by a-chymotrypsin was the most efficient combination of enzymes to reduce allergenicity of α-lactalbumin and β-lactoglobulin (page 3, lines 2-5). O'Callaghan et al teaches that enzymatic hydrolysis of whey protein leads to reduced allergenicity of α-lactalbumin and β-lactoglobulin. Whey protein as a whole has these proteins. Further, O'Callaghan teaches a process for the production of a hypoallergenic whey protein hydrolysate comprising hydrolyzing a substrate with a proteolytic enzyme, thermally inactivating the enzyme and microfiltering the product of hydrolysis (page 6, lines 3-6). The reference further teaches that the invention provides a hypoallergenic whey protein hydrolysates comprising peptide which range in molecular weight from free amino acids to 50,000 Daltons…may also comprise lactose (page 6, lines 22-24). Since the claims are drawn to an active method comprising the step of orally administering to the subject an edible composition an effective amount of a whey protein hydrolysates, and the patient population can be anybody, this implies that the edible composition can be an infant formula or special dietetic composition, as taught by O'Callaghan et al. The combination of references teaches all of the limitations (whey protein hydrolysates being orally administered) of the instant application. In regards to Applicant's argument that Tables 2, 4, 6, 8 and 10 (of O'Callaghan reference) contain only a minor fraction of

material having a molecular weight in excess of 5,000 Daltons, O'Callaghan teaches different ranges of whey protein hydrolysates profile. Therefore, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal component ratios for the hydrolysates of β-lactoglobulin and α-lactalbumin administered in the claimed method of O'Callaghan reference. Component ratio and optimization of concentration of known components (whey protein profile) is an art-recognized result-effective variable which is routinely determined and optimized in the food and drug arts. Controlling glucose homeostasis (blood/sugar regulation) will regulate the availability of glucose to maximize its energy (ATP) making potential in the body. Because the same active agent is being administered to the same subject according to the same method steps, mental performance, sustained feeling of energy or maintaining or providing a feeling of well-being would necessarily be improved in the subject of the prior arts to the same extent claimed by Applicants. Therefore, the whey protein hydrolysates taught by Reimer et al and O'Callaghan et al would necessarily have all of the characteristics and functionality as the claimed whey protein hydrolysate.

In response to applicant's argument that a hypoallergenic whey protein hydrolysates taught by O'Callaghan in the method as taught by Reimer, this would not have led such person to the subject matter of the present claim, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In response to applicant's argument that the examiner's conclusion of

obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, the rejection is maintained.

Obvious Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

14. A timely filed terminal disclaimer in compliance with 37 CFR 1.321© or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

15. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 3-10, 12-13 and 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-

5 and 7-9 of copending Application No. 10/519,657 (US PG Pub 2005/0238694 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant application, one would necessarily lead to the claimed invention of the co-pending application and vice versa.

17. The instant claims are drawn to a method of improving or preventing decline in mental performance, providing a sustained feeling of energy or maintaining or providing a feeling of well being during the post-prandial period in a subject comprising the step of orally administering to the subject by means of an edible composition an effective amount of a whey protein hydrolysates.

18. The claims of copending application are drawn to the method of treating and/or preventing obesity or being overweight in/of a human subject, said method comprising administering to the human subject an edible composition comprising an effective amount of whey protein hydrolysates, to induce the cellular release of glucagon-like peptides and cholecystokinins, said whey protein hydrolysates having a molecular weight profile as measured by SEC-HPLC of 30 to 45% greater than 10,000 Dalton, 7 to 12% in the range 5000 to 1000 Dalton, 15 to 25% in the range 2000 to 5000 Dalton and 30-45% less than 2000 Dalton, use of a whey protein hydrolysates in an edible composition, the whey protein hydrolysates being able to induce the cellular release of glucagons-like peptides and cholecystokinins, wherein the whey protein hydrolysates induces an enhanced feeling of satiety (claims 1, 3-5 and 7-9).

19. If one of ordinary skill in the art practiced the claimed invention of instant application, one would necessarily achieve the claimed invention of the copending application, and vice versa, because the same active agent is being administered to the same subject (anybody) according to the same active method steps. Because the same active agent is being administered to the same subject according to the same method steps, it would necessarily improve decline in mental performance, provide a sustained feeling of energy or maintain or providing a feeling of well-being. Sufficient evidence of similarity is deemed to be present between the claimed method of the '657 application and the instant claimed method to shift the burden to Applicants to provide evidence that their claimed method is unobviously different than the claimed method of the '657 application. Further, the instant application claims its method as part of a dietary plan or a weight management program (see claim 7).

20. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicant's Arguments

21. No response was filed for the provisional double patenting rejection. Applicant indicated that Applicant is willing to file a terminal disclaimer upon indication of allowable subject matter on response filed on April 28, 2008.

22. Until a properly executed terminal disclaimer is filed and approved by the Office, Obviousness Double Patenting rejection is maintained.

New Rejection-35 U.S.C. 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

24. Claims 1, 3-10, 12-13 and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerhardt et al (US 2005/0238694 A1).

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

25. Gerhardt et al teach a method of treating and/or preventing obesity or being overweight in/of a human subject, the method comprising administering to the human subject an edible composition comprising an effective amount of whey protein hydrolysates (WPH), to induce the cellular release of glucagon-like peptides and cholecystokinins, said whey protein hydrolysates having a molecular weight profile as measured by SEC-HPLC of 30 to 45% greater than 10,000 Dalton, 7 to 12% in the range 5000 to 1000 Dalton, 15 to 25% in the range 2000 to 5000 Dalton and 30-45%

less than 2000 Dalton, use of a whey protein hydrolysates in an edible composition, the whey protein hydrolysates being able to induce the cellular release of glucagons-like peptides and cholecystokinins, wherein the whey protein hydrolysates induces an enhanced feeling of satiety (see paragraph [0116] for example). The reference teaches that WPH may have a degree of hydrolysis in the range of up to 20%, from 1 to 15%, 2 to 10%, 5 to 9% (see paragraph [0066]). Furthermore, the reference teaches that WP and WPH have a pH in the range of from 6 to 9 at 20ºC in a 10 mg/ml solution in de-ionized water, more preferably of from 6.5 to 8 (see paragraph [0068]). Further, the reference teaches that suitable food composition may be suitably selected from dairy based products, soy based products, ice creams, desserts, soups, powdered soup concentrate and so on (see paragraph [0082]). Additionally, the reference teaches that a liquid or flowable edible composition 0.1 to 80% by weight base on the weight of the composition of WHP capable of inducing the cellular release of GLP-1 and cholecystokinins (see paragraph [0037]). Because the same active agent is being administered to the same subject according to the same method steps, inherently mental performance, sustained feeling of energy or maintaining or providing a feeling of well-being will be improved in the claimed method of the ‘657 application to the same extent claimed by Applicants. Therefore, the reference anticipates instant claims 1, 3-10, 12-13 and 15-17.

35 U.S.C. 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

27. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

28. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

29. Claims 1, 3-6, 8-10, 12-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al (US Patent No. 6,630,320, filed with IDS 1/14/2009).

30. Davis et al teach orally administering to mammals a composition comprising hydrolyzed whey proteins. The composition comprises whey proteins, including β-lactoglobulin and α-lactalbumin. Davis teaches that the composition in powder form can be dissolved in PBS for oral administration (see abstract, column 2, lines 15-17, for example). Davis teaches a treatment regimen for a mammal to reduce symptoms of hypertension, regimen comprising orally administering to the mammal a whey protein hydrolysates, wherein the hydrolysates has molecular weight profiles within the ranges 50-60% of > 10,000 Daltons, 10-20% of 5,000-10,000 Daltons, 10-20% of 2,000-5,000 Daltons, and 10-20% of < 2,000 Daltons (see claim 1). Since a person suffering from hypertension would benefit from improvement of mental performance, sustained feeling of energy, and maintaining a feeling of well-being, composition of Davis et al would necessarily improve the mental performance. Sufficient evidence of similarity is deemed to be present between the method of Davis et al and Applicant's claimed method shift the burden to Applicants to provide evidence that Applicant's claimed method is unobviously different than the method of Davis et al. Davis teaches that the degree of whey protein hydrolysates of 4.5-6.5%, for example (see column 5, lines 50-53). Davis teaches whey protein hydrolysates in PBS having pH 7.2 (see FIG. 4, for example). The difference between the reference and the instant application is that the reference does not teach 30-45% greater than 10,000 Dalton, 7-12% in the range of 5,000-10,000 Daltons, 15-25% in the range of 2,000-5000 Daltons, and 30-45% less than 2,000 Daltons.

31. However, it would have been obvious to one of ordinary skill in the art to determine all operable weight % of whey range, and optimize the weight % range of the whey protein hydrolysates for improvement of mental performance, providing sustained feeling of energy and well-being. Since the claims are drawn to an active method comprising the step of orally administering to the subject an edible composition an effective amount of a whey protein hydrolysates, and the patient population can be anybody, this implies that the edible composition can be a regimen to reduce symptoms of hypertension. One of ordinary skill in the art would have been motivated to optimize the whey protein hydrolysates range since the hydrolysate profile of Davis reference was successful. It would have been obvious to the skilled artisan to optimize the concentration of whey protein hydrolysates in the composition in order to effectively induce GLP-1 secretion and control glucose homeostasis in the subject. Section 2144.05 of the MPEP states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* In re Aller, *220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at

1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"); *In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)* (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). There is a reasonable expectation of success, since optimization of components is an art-recognized result-effective variable which is routinely determined and optimized in the food and drug arts.

32. Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

33. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654